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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/100,812	06/19/1998	MICHAEL WAYNE GRAHAM	11535	8963

7590 02/15/2002  
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GARDEN CITY, NY 11530

EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/15/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/100,812

Applicant(s)

GRAHAM, MICHAEL WAYNE

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 15 August 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1-4 and 34-45.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 2. NOTE: the scope of recent amendment filed on 12/31/01 encompasses plant cells which would require further consideration and/or search under 35 USC 102 and/or 35 USC 103 regarding prior art issues.

Continuation of 5. does NOT place the application in condition for allowance because:

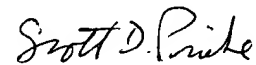
Claims 1-4 and 34-45 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the same reasons of record as set forth in the official action mailed on 02/12/01.

The applicant argues that in light of teaching provided in the present specification and established prior art methodologies those skilled in the art are fully enabled to make and use the invention as claimed without undue experimentation. (response, page 5, 2). The applicant further argues that the specification provides the definition for term "gene, structural gene and target gene". The applicant further argues that the principal feature of the claimed synthetic gene and genetic construct is a combination of multiple structural gene sequences each of which comprises a nucleic acid substantially identical to a target gene in a cell (response, page 4, 2).

However, this is found unpersuasive because the applicant's arguments regarding the definition of "gene" were clearly addressed in the earlier office action mailed on 02/11/01 (pages 2-3) and 05/10/00 (pages 4-5). The instant specification fails to describe a single working example that demonstrates that the expression of any synthetic gene in an animal cell via a viral or a non-viral vector results in the delay, repression or reduction of any target gene expression. In addition, it is general knowledge in the art that different genes have divergent functions. The invention as claimed reads upon a combination of multiple gene sequences, wherein the role of each component has not been described. It is not clear how one skilled in the art would use the invention as claimed to modify an unknown target gene in an animal cell without any guidance provided in the instant specification.

Applicant's argument alone cannot take place of evidence lacking in the record (see *In re Scarbrough* 182 USPQ, (CCPA) 1979). The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). The courts have clearly stated that: "A specification did not disclose what is well known in the art. See, e.g., *Hybritech Inc. V. Monoclonal Antibodies, Inc.*, 802 F. 2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general off-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific material or of any of the conditions under which a process can be carried out, undue experimentation is required: there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". *Genentech Inc. V. Novo Nordisk A/S*, 42 USPQ2d 1005 (CAFC 1997).

In instant case without sufficient guidance to any and all combinations of multiple gene sequences (as claimed), wherein the role of each component has not been specifically ascribed to modify an unknown target gene in a cell is not considered routine and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh*, 17 USPQ2d 1714 (BPAI 1991). Therefore, one skilled in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed.



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